

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application for:

David J. SCHANZLIN et al.

Serial No.: 08/993,696

Filing Date: December 18, 1997

For: RADIAL INTRASTROMAL  
CORNEAL INSERT

Examiner: Dave Willse

Art Unit: 3738

**DECLARATION**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, Pam Golden f/k/a Pam Pascual, declare as follows:

1. That from April 30, 2001 to the present, I have been employed by the law firm of Bingham McCutchen LLP (formerly McCutchen Doyle Brown & Enersen LLP), Three Embarcadero Center, Suite 1800, San Francisco, California 94111-4067.

2. I have been employed as a patent secretary for at least fourteen (14) years, and therefore have prior knowledge of the requirements of 37 C.F.R. § 1.8. I am the Pam Golden f/k/a Pam Pascual, who signed and dated the certificate of mailing (copy attached) on January 7, 2002.

3. That on January 7, 2002, while employed by McCutchen Doyle Brown & Enersen LLP, I did file with the Assistant Commissioner of Patents, Washington, DC 20231, by depositing with the McCutchen Doyle Brown & Enersen mail system an

envelope containing the documents itemized below(copies attached). This envelope was addressed to the Assistant Commissioner of Patents, Washington, D.C. 20231 and I had a reasonable basis to expect that this envelope would be transmitted to the Assistant Commissioner of Patents, with sufficient postage as first class mail, on January 7, 2002. Mail deposited with the McCutchen Doyle Brown & Enersen mail system is routinely picked up at the end of the day and the US Postal Service picks it up on that day. If a pickup was missed, the envelope would have been returned so that I could personally mail the envelope or alternatively, returned to correct the 37 C.F.R. §1.8 date whereupon an appropriate indication would have been made to the file. In any event the envelope would have reached the U.S. Patent and Trademark Office and the post card would have been returned bearing a stamp showing receipt at the USPTO.

4. This envelope contained the following documents for filing in connection with the above-identified non-provisional application:

Response and Fee Transmittal, Preliminary Amendment and Request to Declare Interference Under 37 C.F.R. § 1.607 and return postcard.

5. That to date the postcard acknowledging receipt of these documents has not been returned as receipted by the Assistant Commissioner for Patents.

6. That all statements made herein are of my own knowledge and are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

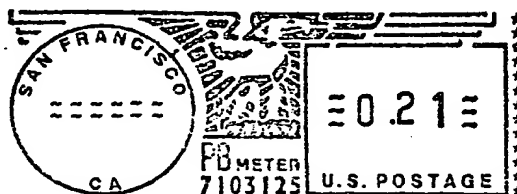
Date: 8-26-02 By: Pam Golden  
Pam Golden f/k/a Pam Pascual

Serial/Patent No.: New Application Filing/Issue Date: Herewith  
Client: David J. Schanzlin, et al. Assignee: Addition Technology  
Title: RADIAL INTRASTROMAL CORNEAL INSERT  
Docket No.: 23915-7316 Atty/Secy Initials: PCJ/tmm  
Date Mailed: January 07, 2002 Docket Due Date: \_\_\_\_\_

*The Following Was Received In The U.S. Patent And Trademark Office On The Date Stamped Hereon:*

- Preliminary Amendment and Request to Declare Interference Under 37 C.F.R. §1.607 (in duplicate, 5 pages);
- Return Receipt Postcard.

21396830.1/23915-7316



**Mr. Robert L. Brandes**  
**Patent and Trademark Administrator**  
**McCutchen, Doyle, Brown & Enersen**  
**Three Embarcadero Center, Suite 1800**  
**San Francisco, CA 94111**

## Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):

[ X ] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington D.C. 20231.

Dated: 1-7-02Name of Person Certifying: Bam Pascua

Printed Name:

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David J. Schanzlin, et al. Assignee: Addition Technology  
 Filing Date: Herewith Examiner: TBA  
 Serial No.: New Application Group Art Unit: TBA  
 Title: RADIAL INTRASTROMAL CORNEAL INSERT

Commissioner for Patents  
 Washington, D.C. 20231

## RESPONSE &amp; FEE TRANSMITTAL

Sir:

Enclosed herewith for filing are the following:

- ☐ A Response/Amendment [ ] page(s)  
☐ A Response to Restriction Requirement under 35 USC § 121 [ ] page(s)  
☐ An Amendment Under 37 CFR § 1.111 [ ] page(s)  
☐ An Amendment Under 37 CFR § 1.116 [ ] page(s)  
☒ Other Preliminary Amendment and Request to Declare Interference Under 37 C.F.R. 1.607 [ 5 ] page(s)

Also included are:

- ☐ A Petition for Extension of Time [ ] months [ ] page(s)  
☐ Information Disclosure Statement  
 [ ] page(s) of PTO-1449 [ ] copies of IDS citations  
☐ Applicant(s) claim Small Entity Status under 37 CFR § 1.27.  
☐ Other: \_\_\_\_\_  
☒ Return Postcard

Fee Calculation						CALCULATIONS
<input type="checkbox"/> The following fees are submitted:						
EXTRA CLAIMS FEE				OTHER THAN SMALL ENTITY	SMALL ENTITY	\$0.00
CLAIMS	CURRENT #	# OF CLAIMS PREVIOUSLY PAID	# EXTRA	RATE	RATE	
Total Claims	- 20			× \$18.00	× \$9.00	\$0.00
Independent claims	- 3			× \$84.00	× \$42.00	\$0.00
MULTIPLE DEPENDENT CLAIM(S)						
<input type="checkbox"/> Yes <input type="checkbox"/> No				\$280.00	\$140.00	\$0.00
Petition for Extension of Time Fee (___ months)						\$0.00
OTHER FEES _____ (specify)						\$0.00
TOTAL FEES =						\$0.00

☒ Conditional Petition for Extension of Time: An extension of time is requested to provide for timely filing if an extension of time is still required after all papers filed with this communication have been considered.

☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

☐ Please charge Deposit Account No. 50-1193, Docket No. \_\_\_\_\_, in the amount of \$ \_\_\_\_\_ to cover the above-fees. *A duplicate copy of this sheet is enclosed.*

☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1193, Docket No. 23915-7316. *A duplicate copy of this sheet is enclosed.*

DATE: 7 January 2002 Respectfully submitted,

By: Patricia Coleman James  
Patricia Coleman James  
Registration No.: 37,155

McCutchen, Doyle, Brown & Enersen, LLP  
Three Embarcadero Center  
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Telephone: (415) 393-2000  
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## Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):

[ X ] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Box Non-Fee Amendment, Washington D.C. 20231.

[ ] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner \_\_\_\_\_ at Facsimile No. \_\_\_\_\_ at \_\_\_\_\_ a.m./p.m.

Dated: 1-7-02 1-7-02 Name of Person Certifying: Pam Pascual  
Printed Name: Pam Pascual

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David J. Schanzlin, et al.  
Filing Date: Herewith  
Serial No.: New Application  
Title: Radial Intrastromal Corneal Insert

Assignee: Addition Technology  
Examiner: TBA  
Group Art Unit: TBA

Commissioner for Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT AND REQUEST TO DECLARE INTERFERENCE**  
**UNDER 37 C.F.R. § 1.607**

**PRELIMINARY AMENDMENT**

Sir:

Please cancel claims 1 to 5, 11 to 13, 22 to 35 and 41 to 49 and kindly amend the subject application by adding the following claims:

-- 50. A method of altering a curvature of a cornea to correct a refractive error, comprising:  
making an initial incision through a corneal epithelium or limbus;  
introducing an intrastromal implant radially into the cornea through the initial incision  
and advancing the implant through a corneal stroma without entering a central optical zone,  
the implant being shaped to substantially correct the refractive error.

51. The method of claim 50, wherein the implant is an elongated member having a long axis which is advanced radially into the corneal stroma, below a corneal epithelium and Bowman's membrane, through the initial incision in the corneal epithelium or limbus, through which initial incision the long axis of the implant is introduced.

52. The method of claim 51, wherein after introduction through the initial incision, the implant is introduced radially into the incision without interrupting Bowman's membrane, and without entering a central optical zone of the cornea.

53. The method of claim 50, wherein the implant is placed in a subject having myopia, and the implant has a curvature greater than the corneal curvature prior to introduction of the implant, to flatten a central curvature of the cornea.

54. The method of claim 50, wherein the implant is placed in a subject having hyperopia, and the implant has a curvature less than the corneal curvature prior to introduction of the implant, to steepen a central curvature of the cornea.

55. The method of claim 50, wherein introducing a stromal implant comprises inserting a plurality of implants into the cornea.

56. The method of claim 55, wherein inserting the plurality of implants comprises radially inserting the plurality of the implants substantially symmetrically about the cornea.

57. The method of claim 55, wherein inserting the plurality of the implants comprises radially inserting the plurality of radial implants asymmetrically about the cornea.

58. The method of claim 57, wherein the plurality of radial implants are introduced asymmetrically into the cornea of a subject having astigmatism.

59. The method of claim 50, further comprising inserting a plurality of the implants radially in the cornea to achieve a desired refractive correction.

60. The method of claim 55, further comprising selectively removing at least one of the implants after they have been introduced into the cornea.

61. The method of claim 51, wherein the implant is elongated, and the method further comprises making a radial tunnel in the cornea below the corneal epithelium, through the initial incision, prior to introducing the implant into the cornea.

62. The method of claim 50, wherein the implant is substantially linear in shape.

63. The method of claim 50, wherein the implant has a tapered leading end that facilitates introduction of the implant into the cornea, and the implant is introduced tapered end first into the cornea.

64. A method of altering a curvature of a cornea to correct a refractive error in a subject, comprising:  
 providing an elongated implant, wherein the implant has a pre-selected curvature or shape, along its longitudinal axis, designed to offset a refractive error in a subject;  
 making an initial incision in a periphery of limbus of the cornea;  
 inserting the implant into a stroma of the cornea through the initial incision, without entering a central optical zone or disrupting the epithelium at other than the initial incision, wherein a greatest width of the implant substantially conforms to the dimensions of the initial incision as the implant is introduced along its longitudinal axis radially into the cornea.

65. The method of claim 51, further comprising injecting the implant into the corneal stroma.

66. The method of claim 64, further comprising forming a stromal tunnel below the epithelium from the initial incision prior to introducing the implant into the cornea.

67. The method of claim 66, wherein forming a stromal tunnel comprises introducing a penetrating member into the cornea. --

### REMARKS

This Preliminary Amendment and Request to Declare Interference is being filed prior to a first office action in the subject application. Original claims 1 to 5, 11 to 13, 22 to 35 and 41 to 49 have been cancelled. New claims 50-67 have been added and are the only claims pending.

### REQUEST FOR INTERFERENCE

It is requested that an interference be declared between the subject application and Sawusch's U.S. Patent No. 6,171,336 B1 ("the '336 patent") issued on January 9, 2001. The subject application is a continuation of U.S. Application No. 08/993,696, filed December 18, 1997 which is a continuation-in-part of U.S. Application No. 08/662,781, filed June 7, 1996 (now abandoned), which is a continuation-in-part of U.S. Application No. 08/485,400, filed June 7, 1995 (now abandoned). Therefore, Applicants' effective filing date is June 7, 1995. The '336 patent was filed on March 25, 1997 and based on its stated priority claim, the effective filing date appears to be March 26, 1996.

Thus Applicants' effective filing date of June 7, 1995 is earlier than the effective filing date March 26, 1996 of the '336 patent.

### COUNT 1

Pursuant to 37 C.F.R. § 1.607 (a) 2, Applicants present the following proposed count 1 for the interference:

**Count 1.** A method of altering a curvature of a cornea to correct a refractive error, comprising:  
making an initial incision through a corneal epithelium or limbus;  
introducing an intrastromal implant radially into the cornea through the initial incision and advancing the implant through a corneal stroma without entering a central optical zone, the implant being shaped to substantially correct the refractive error.

Proposed count 1 is claim 1 of the '336 patent. At least claims 1, 2, 3, 7, 8, 9, 10, 11, 12, 15, 16, 17, 19, 20 and 25 of the '336 patent and Applicants' claims 50-63 and 65 (which have been copied from the '336 patent) correspond to the proposed count 1.



The terms of application claims corresponding to the proposed count are supported in Applicants' original specification at least as follows:

The '336 Patent Claim	Pending Claim	Supporting Language in U.S. Application No. 08/485,400 (page and line number)
1	50	P. 4 L. 1-7 ; P. 9 L. 19-24 ; P. 22 L. 27-30 ; Fig. 23-24
2	51	P.4 L. 1-7 ; P. 21 L. 15-25
3	52	P.4 L. 1-7 ; P. 21 L. 15-25
7	53	P.9 L. 23-30 ; P. 10 L. 1-2 ; P. 16 L. 21-25 ; Fig. 18
8	54	P.9 L. 22-26 ; P. 10 L. 11-12
9	55	P.3 L. 22-28
10	56	P.3 L. 22-28 ; P. 10 L. 28-30 ; Fig. 3A-C
11	57	P.3 L. 22-28 ; P. 10 L. 29-30 ; P. 11 L. 1-4 ; Fig. 3B-C
12	58	P.4 L. 29-30 ; P. 5 L. 1-2 ; P.9 L. 30 ; P.5 L.1-2 ; P. 16 L. 21-25 ; Fig. 18
15	59	P. 3 L. 22-28
16	60	P. 19 L. 21-23
17	61	P.4 L. 20-27 ; P. 16 L. 21-25
19	62	P.11 L. 17-23
20	63	P.11 L. 17-23 ; P. 13 L. 7-11 ; P. 15 L. 17-19 ; Fig. 11, 12
25	65	P.19 L. 24-30 ; P. 20 L. 1-2

### COUNT 2

Pursuant to 37 C.F.R. § 1.607 (a) 2, Applicants present the following proposed count 2 for the interference:

**Count 2.** A method of altering a curvature of a cornea to correct a refractive error in a subject, comprising:  
 providing an elongated implant, wherein the implant has a pre-selected curvature or shape, along its longitudinal axis, designed to offset a refractive error in a subject;  
 making an initial incision in a periphery of limbus of the cornea;  
 inserting the implant into a stroma of the cornea through the initial incision, without entering a central optical zone or disrupting the epithelium at other than the initial incision, wherein a greatest width of the implant substantially conforms to the dimensions of the initial incision as the implant is introduced along its longitudinal axis radially into the cornea.

Proposed count 2 is claim 22 of the '336 patent. At least claims 22, 27 and 28 of the '336 patent and Applicants' claims 64, 66 and 67 (which have been copied from the '336 patent) correspond to the proposed count 2.

The terms of application claims corresponding to the proposed count are supported in Applicants' specification (as originally filed) at least as follows:

The ' 336 Patent Claim	Pending Claim	Supporting Language in U.S. Application No. 08/485,400
22	64	P.21 L. 18-25 ; P. 11 L. 17-33
27	66	P. 21 L. 15-25 ; Fig. 21
28	67	P. 21 L. 15-25 ; Fig. 21

DATE: <sup>PCJ</sup> 7 January 2002

Respectfully submitted,  
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